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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
7379M/MH		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/00790	12/01/2000	20/01/1999
International Patent Classification (IPC) or national classification and IPC G01N33/68		
Applicant THE PROCTER & GAMBLE COMPANY et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04/08/2000	10.01.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Moreno de Vega, C Telephone No. +49 89 2399 7486

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/00790

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-24 as originally filed

Claims, No.:

1-10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Article 33(2) PCT
   Claims 1-10 appear to be novel. The known prior art documents disclose neither the method of determining the aminoacid sequence of a polypeptide comprising derivatizing the N-terminus of the polypeptide with acidic moieties having pKas of less than 2 and analysing the derivatization analytes using a mass spectrometric (MS) technique, nor the kit therefor.
   Thus, claims 1-10 meet the requirements of Article 33(2) PCT.

2. Article 33(3) PCT
   Claims 1-10 appear to be inventive. The technical problem to be solved by these claims is the provision of a MS method and a kit for sequencing polypeptides that is simple, efficient and widely applicable. The solution provided by these claims is based on the discovery that acidic moieties having a pKa of less than 2 when coupled with a polypeptide or peptide thereof will yield fragmentation patterns which are easily to interpret. There is no hint in the known prior art to arrive at the solution proposed by claims 1-10, which therefore meet the requirements of Article 33(3) PCT.

3. The intermediate document:
   D1: KEOUGH, T.; YOUNGQUIST, R. S.; LACEY, M. P.: 'A method for high-sensitivity peptide sequencing using postsource decay matrix-assisted laser desorption ionization mass spectrometry' PROC. NATL. ACAD. SCI. U. S. A., vol. 96, June 1999 (1999-06), pages 7131-7136,
   would appear to disclose the subject-matter of claims 1-10.

   However, the priority of the present application is validly claimed, and therefore this document is not considered to be prior art (Rule 64.1 PCT).

Re Item VII

Certain defects in the international application

1. Reference to prior art being incorporated by reference is not allowed, as the application should be self-contained. Therefore, sentences like "...are incorporated herein by reference" in page 4 lines 29-30 contravene Guidelines C II, 4.17 PCT

2. The attention of the applicant is drawn to the fact that expressions like "preferably", "for example", etc. have no limiting effect on the scope of a claim, that is to say, the feature following any such expression is to be regarded as entirely optional (Guidelines C II, 4.6 PCT).

Re Item VIII

Certain observations on the international application

Claims 1-10 do not meet the requirements of Article 6 PCT, in that the feature "one or more acidic moieties having pKas of less that 2..." is not clear, because in the claims there is no indication to the method of determination of said pKas.
Furthermore, the present application fails to comply with the requirements of Article 5 in that in the description there is no measure of pKa of the acidic moieties employed in the method, thus resulting in lack of support of an essential feature of the claims.